Reporting of Adverse Events to IRBs

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Columbia, Maryland
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Authority of the IRB

IRB authority is limited

- Suspend or terminate study approval
- Change consent form*
- Change protocol *

*Creates inconsistencies for multi-site studies

Type of Information that would be useful to IRBs

- The sponsor's current thinking as to what action should be taken in response to this unexpected event
  - Should the protocol be changed?
  - Should the informed consent form be changed?
  - Should the study be stopped?

Type of Information that would be useful to IRBs

- A copy of the sponsor's review and evaluation that must be submitted to FDA:
  - The sponsor shall promptly review all information relevant to the safety of the drug ... from any source

21 CFR 312.32(b)

Type of Information that would be useful to IRBs

- The sponsor shall notify FDA and all participating investigators in a written IND safety report
  - Any experience that is both serious and unexpected

21 CFR 312.32(c)(1)(i)(A)

... and shall analyze the significance of the adverse experience ...

21 CFR 312.32(c)(1)(ii)

Type of Information that would be useful to IRBs

- A copy of the sponsor's review and evaluation that must be submitted to FDA:
  - A sponsor shall immediately evaluate any UADE

21 CFR 812.46(b)(1)

... shall report the results of such evaluation to FDA and to all reviewing IRBs and participating investigators within 10 working days

21 CFR 812.150(b)(1)

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Type of Information that is not useful to IRBs

- Any unanticipated problem

  21 CFR 56.108(b)(1)
  21 CFR 56.312.66

- The term "serious and unexpected" clearly defines and limits incidents that should be reported
- The term "any unanticipated problem" is open-ended and subject to interpretation that it is unlimited – that any event, no matter how trivial, must be reported to the IRB

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